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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,684	08/03/2001	Jorn Bullerdiek	BOH6277P0001	6746
32116	7590	03/13/2006	EXAMINER	
WOOD, PHILLIPS, KATZ, CLARK & MORTIMER 500 W. MADISON STREET SUITE 3800 CHICAGO, IL 60661			LIETO, LOUIS D	
			ART UNIT	PAPER NUMBER
			1632	
DATE MAILED: 03/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/890,684	Applicant(s) BULLERDIEK, JORN	
	Examiner Louis D. Lieto	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-85 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 48-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 48-61,64-71, 73, drawn to use of a preparation which contains an antiviral vaccine to produce a medicament for preventing and/or treating mesenchymal tissue changes, wherein at least one cell of said tissue is infected with a virus.

Group II, claim(s) 48-61,64-69,72,73, drawn to use of a preparation which contains an antiviral antibody to produce a medicament for preventing and/or treating mesenchymal tissue changes, wherein at least one cell of said tissue is infected with a virus.

Group III, claim(s) 48-61,64-69,73 drawn to use of a preparation which contains an antiviral preparation that inhibits replication, transcription or translation of viral genes in particular genes of adenovirus and/or herpes viruses, to produce a medicament for preventing and/or treating mesenchymal tissue changes, wherein at least one cell of said tissue is infected with a virus.

Group IV, claim(s) 48-61,64-69,73, drawn to use of a preparation which contains an antiviral preparation that recognizes and or destroys cells infected by viruses to produce a medicament for preventing and/or treating mesenchymal tissue changes, wherein at least one cell of said tissue is infected with a virus.

Group V, claim(s) 48-61,64-69,73, drawn to use of a preparation which contains an antiviral preparation which achieves an antiviral effect by their effector-cell-stimulating action to produce a medicament for preventing and/or treating mesenchymal tissue changes, wherein at least one cell of said tissue is infected with a virus.

Group VI, claim(s) 62-71, 73, drawn to use of a preparation which contains an antiviral vaccine to produce a medicament for preventing and/or treating epithelial tissue changes, wherein at least one cell of said tissue is infected with a virus.

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Group VII, claim(s) 62-69,72,73, drawn to use of a preparation which contains an antiviral antibody to produce a medicament for preventing and/or treating epithelial tissue changes, wherein at least one cell of said tissue is infected with a virus.

Group VIII, claim(s) 62-69,73, drawn to use of a preparation which contains an antiviral preparation that inhibits replication, transcription or translation of viral genes in particular genes of adenovirus and/or herpes viruses, to produce a medicament for preventing and/or treating epithelial tissue changes, wherein at least one cell of said tissue is infected with a virus.

Group IX, claim(s) 62-69,73, drawn to use of a preparation which contains an antiviral preparation that recognizes and or destroys cells infected by viruses to produce a medicament for preventing and/or treating epithelial tissue changes, wherein at least one cell of said tissue is infected with a virus.

Group X, claim(s) 62-69,73, drawn to use of a preparation which contains an antiviral preparation which achieves an antiviral effect by their effector-cell-stimulating action to produce a medicament for preventing and/or treating epithelial tissue changes, wherein at least one cell of said tissue is infected with a virus.

Group XI, claim(s) 74,77,78,79, drawn to use of a method to determine an antiviral agent to produce a preparation for preventing and/or treating tissue changes.

Group XII, claim(s) 75,77,78,79, drawn to use of a method comprising carrying out a PCR test in which the primer pairs used for the PCR conform to the sequence of viral nucleic acids in order to determine viruses.

Group XIII, claim(s) 76,-79, drawn to use of a method comprising setting up a cDNA library of a tissue and screening the cDNA library.

Group XIV, claim(s) 80-82, drawn to use of a device for determining a virus involved in the pathogenesis of tissue changes.

Group XV, claim(s) 83-85, drawn to use of a diagnostic method by examining a body fluid for antibodies against viruses.

The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions I-XV lack a unifying special technical feature. International Patent Publication WO

98/21202 (22.05.98) discloses methods of preparation and use of benzo-heterocyclic distamycin

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derivatives used as agents for treating tumors of mesenchymal origin such as soft tissue tumors, bone tumors and leukemia (page 17, lines 1-57; see http://edcenter.med.cornell.edu/CUMC_PathNotes/Neoplasia/Neoplasia_01.html). The distamycin derivatives possess antiviral properties against oncogenic viruses such as Herpes virus, adenovirus and leukemia virus (page 18, line 24), which are known to participate in the formation of tumors of mesenchymal origin and which occur in cancerous cells of tumors of mesenchymal origin (see http://edcenter.med.cornell.edu/CUMC_PathNotes/Neoplasia/Neoplasia_04.html).

Since the special technical feature was known from the prior art document International Patent Publication WO 98/21202, the subject matters of claims 48-85 are not so linked as to form a single general inventive concept (Rule 13.1 PCT) as they appear not to be linked by a new and inventive common special technical feature in the sense of Rule 13.2 PCT by taking into account the state of the art.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a) leiomyomas
- b) endometrial polyps
- c) endometriosis
- d) fibroadenomas
- e) phyllodes tumors

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- f) hamartomas
- g) prostate adenomas
- h) lipomas
- i) angiomyxomas
- j) echondromas
- k) pleomorphic adenomas
- l) colon polyps
- m) atheromas
- n) carcinomas

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 48-85

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical

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features for the following reasons: each of the above tissue changes involves patentably distinct morphological changes and originates from diverse native cell types.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto
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